Significant ADHD Symptom Improvement with 30-Minute Onset and 13-Hour Duration of Efficacy Delivered by Once-Daily Corium Product AZSTARYS® (serdexmethylphenidate and dexmethylphenidate) in Children Ages 6 to 12 Years

First and Only Product Containing Prodrug of Dexmethylphenidate

Complete Phase 3 Trial Data Reported in Journal of Child and Adolescent Psychopharmacology

Boston, MA, October 29, 2021 – Corium, Inc., a commercial-stage biopharmaceutical company leading the development and commercialization of novel central nervous system (CNS) therapies, announced publication of results from its Phase 3 pivotal efficacy study in the November 2021 *Journal of Child and Adolescent Psychopharmacology*. The study showed that Corium's first-in-class, once-daily oral capsule AZSTARYS (serdexmethylphenidate [SDX] and dexmethylphenidate [d-MPH]) significantly improved attention deficit hyperactivity disorder (ADHD) symptoms compared to placebo in children ages 6 to 12 years with a 30-minute onset, 13-hour duration of efficacy, and well-tolerated safety profile comparable to that observed with other stimulant medications. Data from this study will be presented at CHADD's *Virtual International Conference on ADHD.*

"The complete results of the pivotal classroom trial in our peer-reviewed publication show how the novel SDX/d-MPH medication AZSTARYS delivers early and prolonged efficacy throughout the treatment day in children and adolescents with ADHD. These findings are clinically meaningful for parents and health care professionals to aid in evaluating and selecting proven ADHD therapies for their children," said co-author Andrew Cutler, MD, Chief Medical Officer at Neuroscience Education Institute and a Clinical Associate Professor of Psychiatry at SUNY Upstate Medical University.

Corium received approval to market AZSTARYS from the U.S. Food and Drug Administration (FDA) as a once-daily treatment of ADHD symptoms in patients aged 6 years and older on March 2, 2021. AZSTARYS is the first and only medicine containing SDX, a prodrug of d-MPH which provides for an extended duration of d-MPH release throughout the day. Corium launched once-daily AZSTARYS in July 2021 with three SDX/immediate-release d-MPH dose strengths of 26.1/5.2 mg, 39.2/7.8 mg, and 52.3/10.4 mg to meet a wide variety of patients' needs.

"We believe the proven fast onset and prolonged efficacy of AZSTARYS provides patients with ADHD and caregivers an alternative to existing products that can take too long to alleviate symptoms or wear off in the afternoon or early evening," said Charles Oh, MD, Chief Medical Officer of Corium. "We want to thank the trial participants and their families for their contributions in helping develop this first-in-class treatment."

For the pivotal Phase 3 trial (NCT03292952), investigators enrolled 155 children 6 to 12 years of age in a three-week, open-label Dose Optimization Phase. 150 of those children were subsequently randomized to a seven-day, double-blind, placebo-controlled treatment period. Efficacy was established for primary and secondary endpoints.

Primary Efficacy Assessment Shows Significant Reduction of ADHD Symptoms

The primary efficacy assessment was the evaluation of classroom behaviors using the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) Rating Scale – Combined (SKAMP-C). The SKAMP scale is a validated measure of subjective impairment of classroom behaviors in children with ADHD, with lower scores representing reduction of symptoms. The mean change from baseline in SKAMP-C scores collected during the laboratory classroom day was significantly better for AZSTARYS compared to placebo, with respective scores of -4.87 vs. 0.54 and a treatment difference of 5.41 ($p<0.001$).

Rapid Onset with Extended Duration of Action for Significant ADHD Symptom Control

To provide clinicians with data comparable to that from studies of other once-daily methylphenidate products, the investigators conducted a *post hoc* analysis of the mean change from pre-dose baseline to each post-dose assessment conducted at 0.5, 1, 2, 4, 8, 10, 12, and 13 hours during the laboratory classroom day. The post-hoc analysis tcs Ciisis

AZSTARYS, a Schedule II therapy, includes a combination of 70 percent SDX (Schedule IV) and 30 percent immediate-release d-MPH (Schedule II). Based on an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of SDX, the U.S. Department of Health and Human Services (HHS) concluded that "SDX is related in action and effect to the

bipolar illness, or depression. New or worse behavior and thought problems or new or worse bipolar illness may occur. New psychotic symptoms (such as seeing or hearing things that are not real, believing things that are not true, being suspicious) or new

For additional safety information, click here for Prescribing Information and Medication Guide and discuss with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Other Recent Corium Developments

In September 2021, Corium closed on a $235 million term loan agreement with Hercules